

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference Case 1088	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/US2004/043541	International filing date ( <i>day/month/year</i> ) 23 December 2004 (23.12.2004)	Priority date ( <i>day/month/year</i> ) 23 December 2003 (23.12.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant TANOX, INC.		

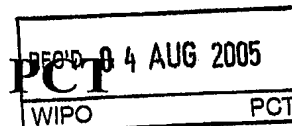
1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).																								
2.	This REPORT consists of a total of 4 sheets, including this cover sheet.  In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report 26 June 2006 (26.06.2006)</p> <p>Authorized officer  Nora Lindner</p> <p>e-mail: pt02@wipo.int</p>
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# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
CHERYL A. LILJESTRAND  
TANOX, INC.  
10301 STELLA LINK ROAD  
HOUSTON, TX 77025



WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) <b>02 AUG 2004</b>		
Applicant's or agent's file reference <b>CASE 1088</b>		
<b>FOR FURTHER ACTION</b> See paragraph 2 below		
International application No. <b>PCT/US04/43541</b>	International filing date (day/month/year) <b>23 December 2004 (23.12.2004)</b>	Priority date (day/month/year) <b>23 December 2003 (23.12.2003)</b>
International Patent Classification (IPC) or both national classification and IPC <b>IPC(7): C07K 16/00; A61K 39/395; G01N 33/53 and US Cl.: 424/130.1, 133.1, 135.1, 156.1; 530350, 387.3, 388.85; 435/7</b>		
Applicant <b>TANOX, INC.</b>		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Christopher Yaen Telephone No. 703-308-0196
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Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/43541

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☒ in written format

☒ in computer readable form

c. time of filing/furnishing

☒ contained in international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US04/43541

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 2, 4, 12-25, 28-31 YES

Claims 1, 3, 5-11, 26-27, 32-33 NO

Inventive step (IS)

Claims 2, 4, 12-25, 28-29 YES

Claims 1, 3, 5-11, 26-27, 30-33 NO

Industrial applicability (IA)

Claims 1-33 YES

Claims NONE NO

2. Citations and explanations:

Claims 1, 3, 5-11, 26-27, 32-33 lack novelty under PCT Article 33(2) as being anticipated by Mak et al (US Patent 6,468,528, issued 10/22/02).

The claims are summarized as a method of treating Hodgkin's lymphoma with an anti-IL-13 antibody that binds glycosylated as well as nonglycosylated IL-13 and neutralizes human IL-13 at a ratio of 1:2 wherein the antibody is a single-chain antibody, administered systemically, and a carrier and a method of diagnosing.

Mak et al teach an anti-IL-13 antibody that binds the polypeptide IL-13 and neutralizes the activity of IL-13 (see column 4) and the antibody can be single-chain, or a whole antibody (which would bind at 1:2 (one antibody and 2 IL-2 for the antibody is bivalent)) and the antibody treats Hodgkin's lymphoma (see column 5-6) and the antibody is in a carrier and can be administered intravenously (see column 7). Since the antibody binds the peptide it would bind glycosylated as well as non-glycosylated IL-13.

Claims 1, 3, 5-11, 26-27, 30-33 lack an inventive step under PCT Article 33(3) as being obvious over Mak et al (above) in view of Thorpe et al (US Patent 6,156,321, issues 12/00).

Claims 30-31 recite a conjugate to the antibody.

Mak et al has been described supra. Mak et al does not teach conjugates of the antibody for treatment. This deficiency is made up for in the teachings of Thorpe et al.

Thorpe et al teach conjugates of toxins and cytotoxic moieties to antibodies for treatment of cancers.

It would have been obvious to conjugate the antibody of Mak et al with a toxin as taught by Thorpe for treatment of cancer.

One would have been motivated because Mak et al teach the antibody targets tumor cells and it would have been obvious to conjugate the antibody to a toxin as taught by Thorpe et al to kill the tumor cells.